UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

RONALDO LIGONS,
BRENT BUCHAN,
LAWRENCE MAXCY,
JOHN ROE and JANE ROE,

Individually, and on behalf of those similarly situated,

Plaintiffs,

V.

MINNESOTA DEPARTMENT OF CORRECTIONS,

THOMAS ROY,
In his official capacity as Commissioner, Minnesota Department of Corrections;

DAVID A. PAULSON, M.D.,
In his official capacity as Medical Director, Minnesota Department of Corrections;

NANETTE LARSON,
In her official capacity as Health Services Director, Minnesota Department of Corrections,

Defendants.

Civil No. 15-2210 (PJS/BRT)

Affidavit of Julie Thompson, M.D.

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Julie Thompson, M.D., states as follows:

1. I am a medical doctor currently serving as an Assistant Professor and Medical Director of Liver Transplantation at the University of Minnesota.
2. I specialize in the diagnosis and treatment of different types of liver diseases, including hepatitis C virus ("HCV"). I am a licensed physician in the State of Minnesota and Board Certified in both Gastroenterology and in Transplant Hepatology.
3. Attached hereto as Ex.1 is a copy of my most recent CV and previous expert reports submitted in this action. (Declarations of Julie Thompson, M.D., October 30, 2016 (ECF 79), March 5, 2018 (Ex.2), March 19, 2018 (Ex 3).

4. Hepatitis C is a serious medical condition, and diagnosis of the disease is the catalyst to begin treatment.

Updated DoC HCV Treatment Guidelines Fail to Meet the HCV Standard of Care

5. The Minnesota Department of Corrections ("DoC") does not follow the community standard of care when it comes to treating prisoners with chronic HCV.
6. The DoC has had iterations of guidelines over the years concerning treatment of patients with chronic HCV and each of these iterations has fallen short of the standard of care. (ECF 79 at ¶17; DOC Ligons.Michaelson 0004075-4077 (Ex. 4); DOC Ligons.Michaelson 0004080-4082 (Ex. 5); DOC Ligons.Michaelson 0004954-4958)(Ex. 6).
7. The DoC has released a new version of its guidelines effective April 12, 2018. (DOC Ligons.Michaelson 0007941-7946)(Ex. 7). This latest iteration is wider in scope concerning intake testing and screening, but it maintains restrictions to treatment, just as previous guideline versions have. (Id.)
8. The April 2018 guidelines move the DoC to begin opt-out testing for chronic HCV rather than opt-in. (DOC Ligons.Michaelson 0007941-7946)(Ex. 7). This testing protocol is only at intake and does not gather information of prisoners who were incarcerated prior to the implementation of the new policy.
9. In the new guidelines, DoC removes prisoners with chronic HCV at fibrosis stages 0 and 1 from consideration for treatment. "[T]he DOC will provide HCV antiviral treatment to offenders who have; Fibrosis stages 2, 3, and 4…". (DOC Ligons.Michaelson 0007941-7946)(Ex. 7).
10. The DoC maintains that prisoners with chronic HCV and fibrosis stage of 0 or 1 are in a stable medical condition and are not eligible for treatment. (Second Paulson Affidavit, ECF

223, ¶91). Patients with minimal fibrosis can sometimes have serious symptoms associated with HCV such as joint pain, fatigue and muscle aches. It is also well established that HCV increases risk of cardiovascular disease, kidney disease diabetes mellitus and lymphomas.

11. The DoC states that the exception for not offering treatment at fibrosis stage 0 or 1 is a prisoner with chronic HCV having a concurrent co-infection with HIV or Hepatitis B. They could be considered for treatment if they also have another disease like diabetes. (DOC Ligons.Michaelson 0007941-7946)(Ex. 7). Without those caveats, prisoners with chronic HCV at fibrosis stage 0 or 1 are deferred treatment and instead monitored at intervals. For fibrosis stage 1, prisoners are tested every year, and for fibrosis stage 0, prisoners are tested every two years. (DOC Ligons.Michaelson 0007941-7946)(Ex. 7). Simply monitoring patients does not constitute treatment. There is no literature that I am aware of that supports, describes, explains, recommends or substantiates such a monitoring scheme without offering treatment. Under the current standard of care, *treatment* means the administration of DAA medications.
12. Despite the changes made to the DoC guidelines, the April 2018 DoC guidelines continue to fall short of the AASLD/IDSA Guidelines that recommend treatment for all patients diagnosed with chronic HCV no matter their fibrosis stage. (AASLD/IDSA Guidelines "When and In Whom to Treat")(Ex. 8).
13. This standard of care is maintained in the community even with patients using the Medicaid system. In my experience patients on MN Care have received treatment and not been prevented by their insurance carrier from accessing DAAs as long as the drug prescribed is on the preferred list. (Thompson Rebuttal Declaration ¶ 9; MHCP Enrolled Providers – Pharmacies, Fee for Service PA Criteria Sheet – Hepatitis C Direct Acting Antivirals, January 2017)(Ex. 9).

Mr. Maxcy has chronic HCV and is at risk for additional comorbidities associated with HCV, as are all HCV infected patients.

14. Of the three named plaintiffs in this case, Mr. Maxcy has yet to be treated with a DAA medication. (Second Paulson Affidavit, ECF 223, ¶125). The DoC claims that he does not need treatment because he has "normal liver function". (Id at ¶126).
15. Mr. Maxcy's latest elastography test was reported as fibrosis level of stage 0. (DOC Ligons.Michaelson 0005858)(Ex. 10). A patient with chronic HCV and a fibrosis stage of 0 cannot necessarily be characterized as having a "normal liver ". The patient--in this case, Mr. Maxcy--continues to have chronic HCV in the liver and HCV can cause other comorbidities even when there is limited or no liver scarring.
16. His diagnosis of chronic HCV has been known to the DoC since at least 2006. Even after requesting medication, the DoC continued to defer his treatment, putting him at risk for progression of chronic HCV and other conditions associated with chronic HCV. (DOC Ligons.Michaelson 0005856 (Ex. 11); DOC Ligons.Michaelson 0007404-7426)(Ex. 12).
17. At every stage of fibrosis in chronic HCV, patients can experience other issues related to HCV. This is true even for those with no or minimal liver scarring.
18. Symptoms commonly associated with chronic HCV include higher reports of fatigue, arthralgia (joint pain), and myalgia (muscle aches). Patients report psychological stress in living with HCV.
19. In my medical practice, I have seen patients who were treated with DAA medication at lower fibrosis stages express positive changes in their health after receiving treatment. Patients have told me that they experience more energy, less joint pain and psychological relief after eradicating HCV.

20. Chronic HCV is also known to confer higher risk of developing diabetes mellitus type 2, cryoglobulinemic vasculitis (an inflammation of the blood vessels that can result in many deleterious effects), B cell lymphomas (2.5 times increased risk), cardiovascular disease and a multitude of kidney disorders which all result in higher risk of chronic kidney disease. (Anne-Claire Desbois & Patrice Cacoub, *Diabetes Mellitus, Insulin Resistance and Hepatitis C Virus Infection: A Contemporary Review*, 23.9 WORLD J. GASTROENTEROLOGY 1697–1711 (2017) (Ex. 13); Francesco Negro & Mahnaz Alaei, *Hepatitis C Virus and Type 2 Diabetes*, 15.13 WORLD J. GASTROENTEROLOGY 1537–1547 (2009)(Ex. 14); Syed Tasleem & Gagan K Sood. *Hepatitis C Associated B-Cell Non-Hodgkin Lymphoma: Clinical Features and the Role of Antiviral Therapy*, 3.2 J. CLINICAL & TRANSLATIONAL HEPATOLOGY 134–139 (2015) (Ex. 15); Laura E. Dowsett, et al, *Living with Hepatitis C Virus: A Systematic Review and Narrative Synthesis of Qualitative Literature*, CAN. J. GASTROENTEROLOGY & HEPATOLOGY (2017), available at PMC:3268650(Ex. 16); Ahmad Najib Azmi, Soek-Siam Tan, & Rosmawati Mohamed. *Hepatitis C and Kidney Disease: An Overview and Approach to Management*, 7.1 WORLD J. HEPATOLOGY 78–92 (2015) (Ex. 17); C.P.M.S Oliveira et al., *Effects of Hepatitis C virus on cardiovascular risk in infected patients: A comparative study*, 164.2 INT'L J. CARDIOLOGY, 221-226 (2013) (Ex. 18)).

21. Along with it being the standard or care, these increased risks of developing other medical conditions highlight the necessity to treat a patient with chronic HCV with DAA medications, even when the patient has mild fibrosis.

Fibrosis testing may not have the test characteristics suitable to determine who receives treatment or not

22. Assessing the level of fibrosis in patients with chronic HCV has been reported using various methods. These include blood tests that attempt to estimate of the presence of liver scarring,

elastography –a specific type of ultrasound that provides an assessment of liver scarring, and liver biopsy—a direct examination of liver tissue to quantify scarring. The primary goal for assessing the degree of fibrosis is to differentiate advanced scarring (F3 or F4) from scarring that is not as advanced (F0, F1, F2). The purpose of this differentiation is for determining which medications may be most effective and for how long that patient needs treatment, as well as to plan follow up needed after HCV cure. These tests were not designed to differentiate for example, F1 from F2, in order to treat or not treat HCV. US elastography is known to perform more poorly at the lower stages of fibrosis (that is, it is less likely to be able to differentiate F0 from F2, than it is to differentiate F2 from F4)

23. A test such as elastography, similar to any medical test, has variabilities and was not designed with the intention of making treatment decisions. The test is not meant to determine whether or not a patient is treated. (Ryosuke Takemoto et al., *Validity of FibroScan values for predicting hepatic fibrosis stage in patients with chronic HCV infection*, 10 J. DIGESTIVE DISEASES 145-148 (2009)(Ex. 19); An Tang et al., *Ultrasound Elastography and MR Elastography for Assessing Liver Fibrosis: Part 2, Diagnostic Performance, Confounders, and Future Directions*, 205 AM. J. ROENTGENOLOGY 33-40 (July 2015) (Ex. 20); Declaration of Julie Thompson, M.D., Ex. 1 ¶14)).

24. All patients diagnosed with chronic HCV are at risk of suffering from further complications of the disease over time. This is why, once diagnosed, a patient with chronic HCV must be prescribed treatment with DAAs, as per standard of care.

Further affiant sayeth not.

Date: May 1, 2018

Dr. Julie Thompson

Subscribed and sworn to before me on this
1 day of May, 2018.

Notary Public

ROBERT REINHARD LANGER
NOTARY PUBLIC - MINNESOTA
MY COMMISSION EXPIRES 01/31/19